Remarks

This Amendment is responsive to the Advisory Action mailed July 12, 2001 (Paper No. 12). Entry of this Amendment and reconsideration of the subject application in view thereof are respectfully requested.

Claims

Claims 1-24 and 26-36 were pending. Claims 1-24 and 26-36 stand rejected.

Claims 1-24 and 26-36 have been amended to more particularly and distinctly define the invention. No new matter is added.

Support

Support for the amendments to the claims is either apparent or as set forth herein. Specifically, support for the recitation of "wherein the disk is made of a mixture of materials" may be found in the specification at, for example, page 12, line 26-28. No new matter is added.

Advisory Action

The Examiner asserts that:

> Applicant argues that the instant claims, since they recite "consisting of" language, do not include an adhesive and therefore is neither anticipated nor obvious over Denzer (6,007,836). However, the claims are not closed as the claims "further comprise" ingredients including a stabilizer, a solubilizer, an enhancer, and a plasticizer. Adhesives fall within these ingredients. Furthermore, one would look to the specification to understand what the disk of the instant claims is. There, one finds that the specification discloses that the disk comprises adhesives..

Applicants have elected to present the invention in different terms, which terms obviate the asserted basis for this rejection. Applicants respectfully point out that Denzer specifically discloses that

> all the patches are provided with an adhesive on the inner, skin-facing surface [of the one or more layers]. The adhesive may be a coating sprayed on, or may be a distinct substrate layer with a tacky surface on both sides.

(See Denzer Col. 7, lines 25-43). Denzer clearly does not anticipate, teach or suggest the device of the claimed invention consisting of a disk, wherein the disk is made of a mixture of materials, wherein the mixture of materials comprises a filmogenic polymer and an effective dose of a therapeutic agent suitable for treating erectile dysfunction. Reconsideration and withdrawal of the outstanding rejections are respectfully requested.

FEE DEFICIENCY

☒ This Paper is believed timely filed. If an extension of time is deemed required for consideration of this paper, please consider this paper to comprise a petition for such an extension of time; The Commissioner is hereby authorized to charge the fee for any such extension to Deposit Account No. 04-0480.

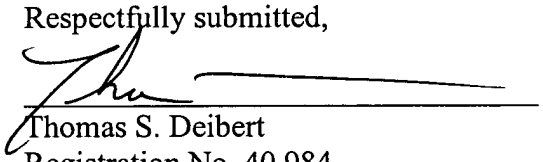
and/or

☒ If any additional fee is required for consideration of this paper, please charge Account No. 04-0480.

Closing Remarks

Applicants thank the Examiner for the Office Action and believe this response to be a full and complete response to such Office Action. Accordingly, favorable reconsideration in view of this response and allowance of the pending claims are earnestly solicited.

Respectfully submitted,



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Detail of claim amendments

1. (Thrice Amended) A delivery device for treatment of erectile dysfunction in a patient, consisting of a disk, wherein the disk is made of a mixture of materials, wherein the mixture of materials comprises [of] a filmogenic polymer[, wherein the disk of filmogenic polymer contains] and an effective dose of a therapeutic agent suitable for treating erectile dysfunction.

2. (Thrice Amended) [A] The delivery device according to claim 1, [comprising further] wherein the mixture of materials further comprises at least one additive [contained within the disk of filmogenic polymer, wherein the at least one additive is] selected from the group consisting of a stabilizer, a solubilizer, an enhancer and a plasticizer.

3. (Once Amended) [A] The delivery device according to claim 1, wherein the therapeutic agent is a prostaglandin.

4. (Once Amended) [A] The delivery device [agent] according to claim 3, wherein the prostaglandin is prostaglandin E1.

5. (Once Amended) [A] The delivery device according to claim 1, wherein the therapeutic agent is selected from the group consisting of: a vasodilator, a smooth muscle relaxant, an anti-depressant, a parasympathetic stimulator, a renin-angiotensin system inhibitor, a local anesthetic, an ∝-blocker, and a calcium channel blocker.

6. (Once Amended) [A] The delivery device according to claim 5, [comprising further] wherein the mixture of materials further comprises at least [an] one additional therapeutic agent.

7. (Twice Amended) [A] The delivery device according to claim 6, wherein the [at least] additional therapeutic agent is selected from the group consisting of: prostaglandin, a

testosterone, a yohimbine, a pentoxifylline, a trazodone, an apomorphine, a sildenafil, a minoxidil, a misoprostol, a papaverine, a nitroglycerin, a phentolamine, a moxisylyte, a linsidomine, a linear peptide, a cyclic peptide, and a pyridylguanidine compound.

8. (Twice Amended) [A] The delivery device according to claim 2, wherein the enhancer is at least one selected from the group consisting of a glycolipid, a non-esterified fatty acid, an aliphatic alcohol, a fatty acid ester of an aliphatic alcohol, a cyclohexanol, a fatty acid ester of glycerol, a glycol, an aliphatic alcohol ether of a glycol, and a surfactant.

9. (Twice Amended) [A] The delivery device according to claim 8, wherein the filmogenic polymer is polyvinyl pyrrolidone, the therapeutic agent is prostaglandin E1, the enhancer is hexyldecyl stearate, and the plasticizer if PEG 400.

10. (Twice Amended) [A] The delivery device according to claim 2, wherein the filmogenic material is present in an amount of 5 to 100%, the therapeutic agent is present in an amount of 0.1 to 20% w/w, the enhancer is present in an amount of 0.01 to 15%, and the plasticizer is present in an amount of 1 to 70%, each on a weight basis.

Claim 11. (Twice Amended) [A] The delivery device according to claim 9, having polyvinyl pyrrolidone present in an amount that is 40 to 45%, having prostaglandin E1 present in an amount that is 5 to 10%, having Eutanol G16S present in an amount that is 1 to 4%, and having PEG 400 present in an amount that is 40 to 50%.

12. (Twice Amended) [A] The delivery device according to claim 9, having polyvinyl pyrrolidone present in an amount that is 40 to 45%, having prostaglandin E1 present in an amount that is 5 to 10%, having hexyldecyl stearate present in an amount that is 1 to 4%, and having PEG 400 present in an amount that is 40 to 50%.

13. (Once Amended) [A] The delivery device according to claim 1, wherein the filmogenic polymer is selected from the group consisting of a synthetic polymer, a semi-synthetic polymer, and a naturally occurring polymer.

14. (Once Amended) [A] The delivery device according to claim 13, wherein the synthetic polymer is polyvinyl pyrrolidone.

15. (Once Amended) [A] The delivery device according to claim 13, wherein the naturally occurring polymer is from a plant.

16. (Once Amended) [A] The delivery device according to claim 15, wherein the plant polymer is a gliadin.

17. (Twice Amended) [A] The delivery device according to claim 2, having a plasticizer in an amount less than 30% on a dry weight basis.

18. (Once Amended) [A] The delivery device according to claim 1, wherein delivery is transdermal.

19. (Once Amended) [A] The delivery device according to claim 1, wherein delivery is transmucosal.

20. (Once Amended) [A] The delivery device according to claim 1, wherein the effective dose is released into the subject within one hour.

21. (Thrice Amended) A method of treating erectile dysfunction, comprising:

selecting a device consisting of a disk, wherein the disk is made of a mixture of materials, wherein the mixture of materials comprises [of] a filmogenic polymer [; wherein the disk of filmogenic polymer contains] and an effective dose of at least one therapeutic agent suitable for treating erectile dysfunction;

wetting a penile surface; and

placing the device in contact with the wetted penile surface delivering the at least one therapeutic agent to the penile surface over an effective period of time.

22. (Twice Amended) [A] The method according to claim 21, wherein [in forming the disk,] the therapeutic agent is selected from the group consisting of a prostaglandin, a testosterone, a yohimbine, a pentoxifylline, a trazodone, an apomorphine, a sildenafil, a minoxidil, a misoprostol, a papaverine, a nitroglycerin, a phentolamine, a moxisylyte, a linsidomine, a linear peptide, a cyclic peptide, and a pyridylguanidine compound.

23. (Once Amended) [A] The method according to claim 21, wherein the therapeutic agent is present in a range of 0.1-15%, on a dry weight basis.

24. (Once Amended) [A] The method according to claim 21, wherein [forming the disk] mixture of materials further comprises [adding] a plasticizer.

26. (Once Amended) [A] The method according to claim 24, wherein the plasticizer is present in an amount that is less than 30% on a dry weight basis [, and delivering the therapeutic agent to the penile surface has the additional step of pre-wetting the surface].

27. (Once Amended) [A] The method according to claim 24, wherein the plasticizer is a polyethylene glycol (PEG).

28. (Once Amended) [A] The method according to claim 27, wherein the PEG is PEG 400.

29. (Once Amended) [A] The method according to claim [29] 21, wherein the [synthetic] filmogenic polymer is a synthetic polymer.

30. (Once Amended) [A] The method according to claim 29, wherein the synthetic polymer is polyvinyl pyrrolidone.

31. (Once Amended) [A] The method according to claim 21, wherein the filmogenic polymer is a plant protein.

32. (Once Amended) [A] The method according to claim 23, wherein the plant protein is a prolamine.

33. (Once Amended) [A] The method according to claim 32, wherein the prolamine is a gliadin.

34. (Once Amended) [A] The method according to claim 21, wherein the effective period of time is 5-100 minutes.

35. (Once Amended) [A] The method according to claim 34, wherein the effective period of time is 30-60 minutes.

36. (Once Amended) [A] The method according to claim 21, wherein the penile surface is selected from the group consisting of the shaft and the glans.